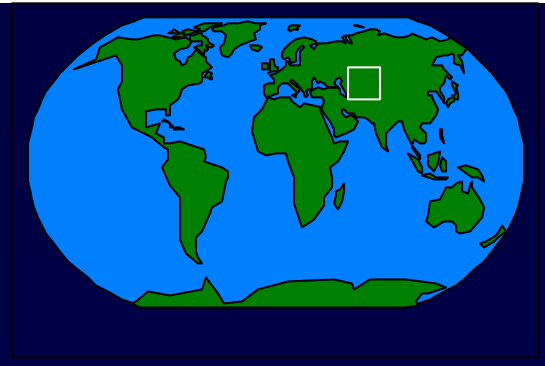
Establishment and Implementation of Comprehensive Training for Laboratory Capacity Building in Central Asia

Kalashnikova T. (DIH, EPO, CDC/CAR)
Musabaev E. (Ref. Lab .Uzbekistan)
Usmanov R. (Ref. Lab. Kyrgyzstan)
Kovtunenko N (RL RC AIDS Kazazhstan)
Suleymenova S.(Ref. Lab Kazakhstan)
Golovchenko N.I.(RL RC AIDS Kyrgyzstan)
Ongarbaev A. (Ref. Lab .Uzbekistan)
Kuchuk T.(Ref. Lab. Kyrgyzstan)
Albetkova A. (Ref. Lab .Uzbekistan)
Jumagulova A. (DIH, EPO, CDC/CAR)
Drobeniuk J. (DVH, NCID, CDC)
Favorov M. (DIH, EPO, CDC/CAR)

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION



World Fact-book

Area: total: 3,994,400 sq km
Climate: dry continental to polar in high Tien Shan; subtropical in Fergana Valley; temperate in foothill zone.
Environment issues: water pollution; many people get their water directly from streams

Population: 55,431,390. Children 0-14 years: 36%.
Birth rate: 22.03 births/1,000 population (1998)
Infant mortality rate: 58-113 deaths/1,000 live births

Economic - poor, countries with predominantly agricultural economy. Several countries in the region reach with national resources. Poor infrastructure limited countries income.
Illicit drugs: limited government eradication program; increasingly used as transshipment point for illicit drugs

CDC
SAFER • HEALTHIER • PEOPLE™
CENTERS FOR DISEASE CONTROL AND PREVENTION

Countries of Central Asia Laboratory Service Limitations

- Absence of national quality assurance system for quality standards
  - Lack of cadre of qualified laboratory specialists
  - Limited resources
  - Outdated facilities and equipment
  - Absence of Quality system for reagents used
- Absence of principles for internal (IQC) and external (EQA/PT) laboratory quality control
- Absence of continuous postgraduate education for laboratory specialists

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Consecutive testing of the serum sample from a single hepatitis B patient

(10 aliquots; One month period; Almaty City Laboratory, Kazakhstan)

Markers/samples	1	2	3	4	5	6	7	8	9	10
Anti-HAV IgM	-	-	-	-	-	-	+	-	-	-
HBsAg	-	+	-	-	-	-	+	+	+	+
Anti-HBs	-	-	-	-	-	-	-	-	-	-
Anti-HBc IgM	+	+	+	+	+	-	-	+	+	-
Anti-HBc	-	-	-	-	-	-	-	-	-	-
HBeAg	-	-	-	-	-	-	-	-	-	-
Anti HBe	-	-	-	-	-	-	-	-	-	-
Anti-HCV IgM	-	+	-	-	-	-	-	+	-	+
Anti-HCV	-	-	-	-	-	+	-	-	-	-
Anti-HCV Core	-	-	-	-	-	-	-	-	-	-
Anti-HCV NS	-	-	-	-	-	-	-	-	-	-
Anti-HDV IgM	-	-	-	-	-	-	-	-	-	+
Anti HDV Total	-	-	-	-	-	-	-	-	+	-
Anti-HEV	-	-	-	-	-	-	+	-	-	-
Anti-HGV	-	-	-	-	-	-	-	-	-	-

(CDC Atlanta Lab. Testing data - HBsAg pos; IgM anti-HBc pos; IgM anti-HAV neg; anti-HCV neg)

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

GOAL

- Establishing and implementation of comprehensive laboratory training to develop quality assurance program focusing on laboratory diagnostic of HIV and viral hepatitis

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Objectives and Methods

Develop Knowledge

- To institute training system for theoretical and practical aspects of Quality assurance for employers of laboratoriy service network
  - basic QA training course
  - Apply Advanced QA Training course

Improve Skills

- To establish of reference-laboratories – QA centers for development and implementation
  - Normative standards
  - Biological standards
- Re-equipment of the leading laboratories on the Republican and Oblast levels
- Implementation quality control test-kits

Increase competence

- Monitoring of test performance quality by implementation
  - Internal quality control program
  - External quality assessment /Proficiency Testing programs

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Knowledge

- **Quality Assurance/Quality Control (QA/QC) manuals was developed for trainings support**
- **23 QA training were provided for 461 participants from different countries of CAR AIDS centers**
  - **Sanitarian surveillance centers**
  - **Blood Donor Centers**
  - **Infectious diseases hospitals**
  - **Private laboratories**
- **Lecturing in quality control have been included to workshops for epidemiologists and practitioners in Central Asia**

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Reference laboratories

- Reference laboratories for HIV and viral hepatitis were established in four states of Central Asia and their responsibilities for implementation QA programs were approved by MOH
  - Kyrgyzstan (1998)
  - Kazakhstan (2000)
  - Uzbekistan (1999)
  - Turkmenistan (2000)
- Develop, distribute, implement QA policy (Prikaz, Rules, Guidelines, Manuals)
- Implement test-kits control on the national level (Kyrgyzstan, Uzbekistan, Kazakhstan,

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

EQUIPMENT

- Forty one sets of ELISA equipment and supplies were purchased in 2004

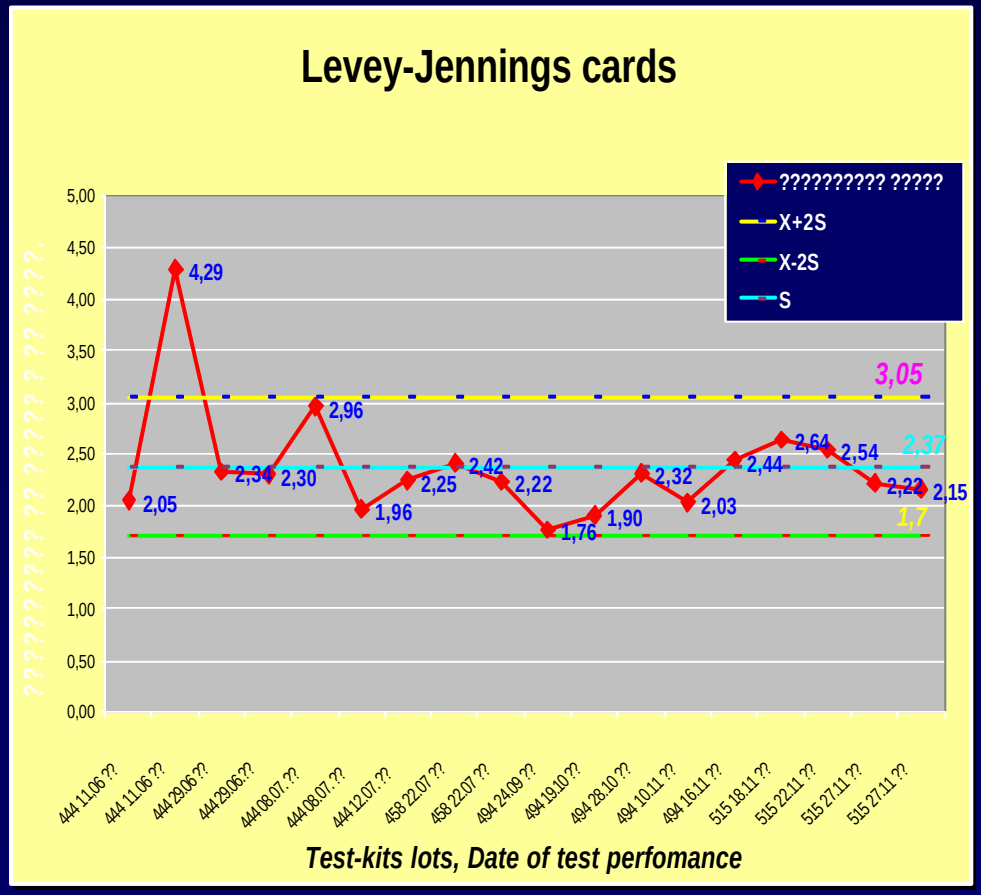
Process of re-equipping

- the list of equipment with it's specifications was created
- technical assistance for installation and initial calibration was provided
- mechanisms for maintenance, service, and repair was set up

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Internal quality control

- Internal quality control program implementation
  - Select specimens, create reference panels
  - Evaluate control results daily and over time
  - Establish and use acceptance criteria



CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Pilot Proficiency Testing programs in CAR

- In Kazakhstan anti HIV reference panel with 6 samples (3 anti-??? positive and 3 anti-HIV negative) were used. 100% accurate results of test performance could achieved .
  - 8 % (2/24 laboratories) in 1998
  - 75 % (18/24 laboratories) in 2001

- In Uzbekistan anti-HCV reference panel with 8 samples (6 anti-HCV positive and 2 anti-HCV negative) was used. 100 % accuracy of test performance could archived
  - 0 % (0/19 laboratories) In 2000
  - 17 % (4/23 laboratories) in 2001

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Current PT programs in CAR

- WHO compliant multi-reference national panels with serological markers of HIV, HBV and HCV infections were created and used in **Kazakzhstan, Uzbekistan, Kyrgyzstan** since 2002

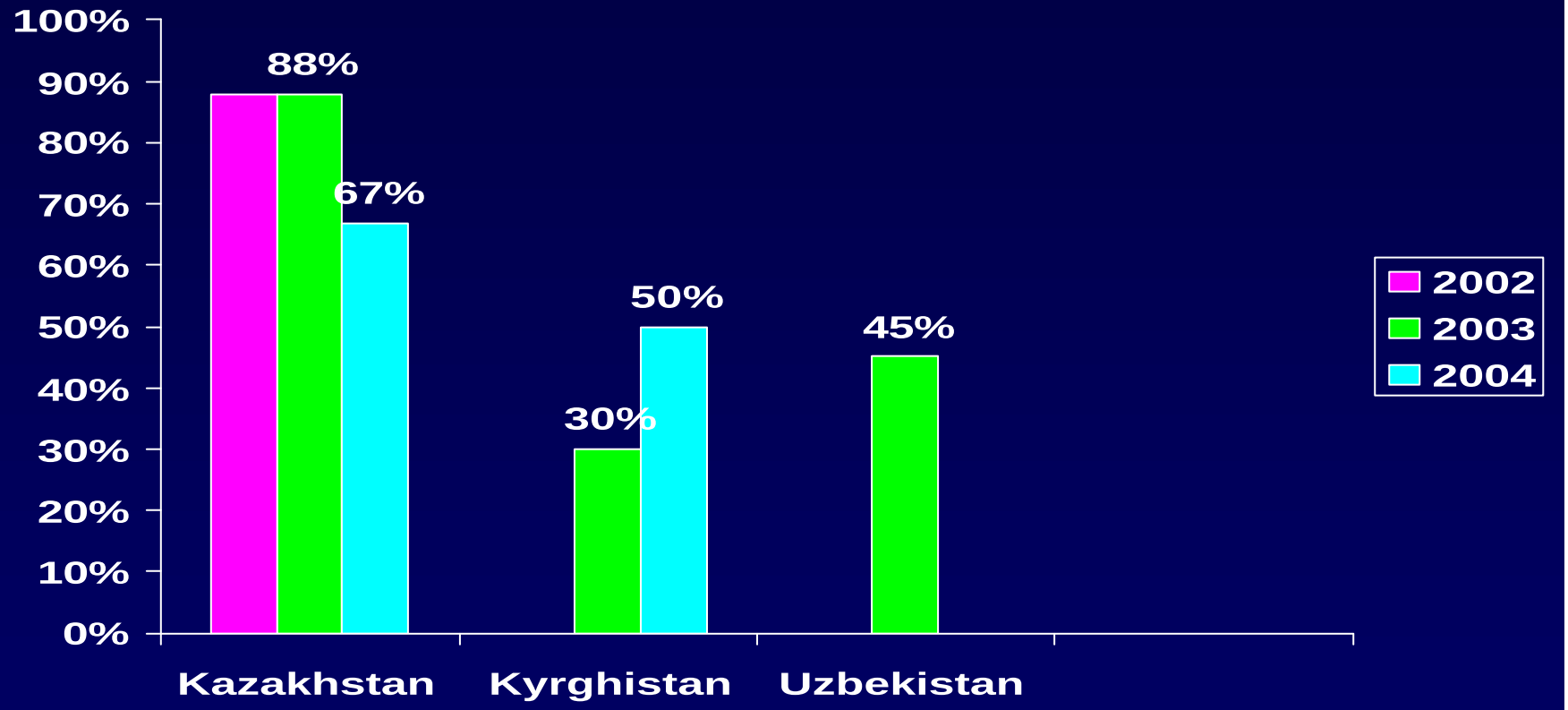
    - [*Requirements and Guidance for External Quality Assessment Schemes for Health Laboratories*, WHO/DIL/LAB/99.2

Design of Multi -reference pattern

- There are 8 specimens in RP.
- Every specimen was tested with test kits, recommended by WHO
  - -"Ortho HIV1/HIV2 Ab-Capture",
  - - "Ortho HCV 3.0", "Ortho -HBsAg" (Ortho-Clinical Diagnostics, USA),
  - "Genscreen HIV1-2 Ag-Ab",
  - "Monolisa HCV",
  - "Monolisa AgHBs" (BioRad, France).
- All the specimens stored at - 20 Cº and transported at 2-8 º? .

# of sample	Type of marker
1	**Anti-HIV high-active (OD/OD crit. =7,2-14,5)**
2	**Anti-HIV Moderate-active (OD/OD crit. =4,9-5,5)**
3	**Anti-HIV low-active (OD/OD crit. =2,3-2,9)**
4	**Anti-HCV Moderate-titered (OD/OD crit. =2,5-3,5)**
5	**Anti-HCV high-titered (OD/OD crit. =5,1-5,6)**
6	**HBsAg (5 ng/ml)**
7	**HBsAg (1 ng/ml)**
8	**HBsAg (0,25 ng/ml)**

Anti-HIV PT programs results



2002-19labs

2003-17 labs

2004-17 labs

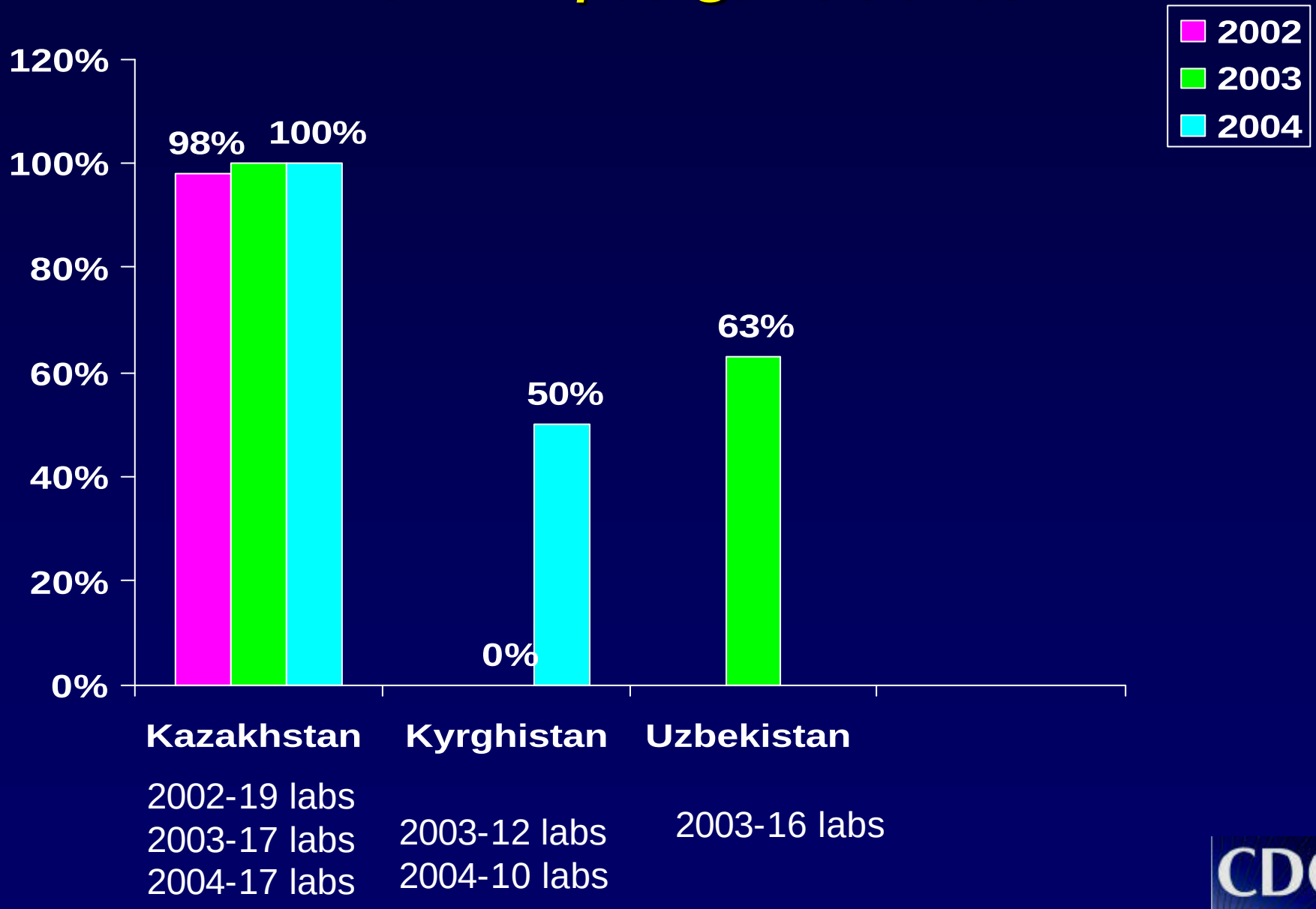
2003-12 labs

2004-10 labs

2003-33 labs

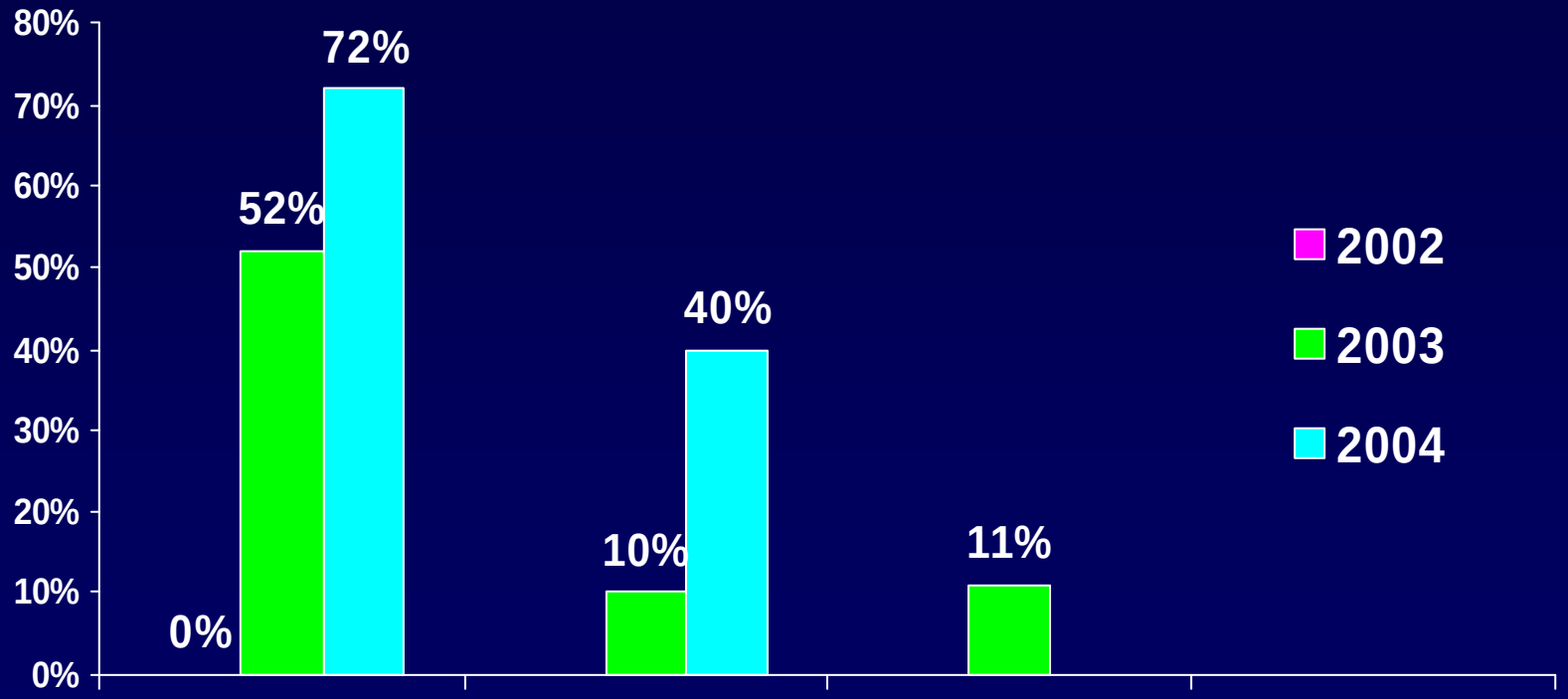
CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Anti-H?V PT programs results



CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

HBsAg PT programs results



2002-19 labs
2003-17 labs
2004-17 labs

2003-12labs
2004-10 labs

2003-26 labs

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

International Proficiency Testing programs participation

- Model Performance Evaluation Program for anti-HIV-1 testing (Department of Laboratory System, CDC Atlanta)
  - 17/19 laboratories of CAR were awarded in 2004
- Proficiency testing program for anti-HIV-1 dried blood spots testing (Department of Laboratory System, CDC Atlanta)
  - 8/8 laboratories of CAR were awarded in 2004

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Conclusions (1)

The training module to establish QA/QC principles in the region has been developed

Reference Laboratories serving as quality assurance methodology centers for the diagnosis of infectious diseases were implemented

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Conclusions (2)

CAR QA/QC Program enables

-

- Reliable HIV and Viral Hepatitis surveillance data in Kazakzhstan, Uzbekistan and Kyrgyzstan
- ID diagnosis test kits quality control implementation
- Monitoring and evaluation of HIV, Viral hepatitis programs in Uzbekistan, Kazakhstan and Kyrgyzstan
- International Proficiency Testing Programs participation for modern laboratory QC process involvement

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION

Recommendation

- **Sustainability of the QA programs in CAR could be achieved by:**
  - ***Implementation of QA issuer (SOP, IQC) in each laboratory of laboratory service network***
  - ***Conducting the regional and interregional EQC/PT program on the regular basis***
  - ***Participation in the international EQC/PT program***
  - ***Development of system of laboratory certification by policy changes in laboratory management and operations***

CDC
CENTERS FOR DISEASE CONTROL AND PREVENTION